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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/544,632	04/06/2000	Goro Hori	506.35379CC2	9269

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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/544,632	HORI ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,18,28-34,38,42,43,45,46 and 48-54* is/are pending in the application.

4a) Of the above claim(s) *18 and 28-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,35,36,38,42,43,45,46 and 48-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment dated 6-22-05 and the affidavit dated 7-15-05 are acknowledged.

Claims included in the prosecution are 18, 35-36, 38, 42-43, 45-46 and 48-54.

Claim Rejections - 35 U.S.C. ' 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 18, 35-36, 38, 42-43, 45-46 and 48-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugano (J. Nutr., 1990) or Sugano (Atherosclerosis, 1988) by themselves or in combination with Imaizumi (Agri. Biol. Chem., 53, (9), 1989 of record.

As pointed out before, the references of Sugano teach the effectiveness of soybean protein-phospholipid complexes in lowering the cholesterol levels (note the

abstracts and Tables in both). The amounts of phospholipids in Sugano however, are lower than the amounts in instant invention.

Imaizumi teaches that the administration of phospholipids causes the reduction in the serum cholesterol levels (note the abstract).

It would have been obvious to alter the amounts of the phospholipids in the phospholipid-soy protein complex in Sugano, with the expectation of obtaining the best possible results, since Imaizumi teaches that phospholipids by themselves lower the cholesterol. The criticality of the enzyme-modified phospholipid is not readily apparent to the examiner; as pointed out above, the specification does not provide a definition or experiments conducted with this product.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant once again argues that both references of Sugano focus on the effect of reducing serum and liver cholesterol by an indigested high molecular fraction of soybean protein obtained after microbial protease digestion and that these references do not teach that the effect is due to the complex of protein and phospholipid. According to applicant, neither of the Sugano, et al. articles would have disclosed, or would have suggested, administering soybean protein together with the enzyme-modified phospholipid much less the complex having at least 10 wt% of the enzyme-modified phospholipid bound in the complex, as in the present claims and that each of the Sugano, et al. articles is silent about soybean protein containing enzyme modified phospholipid, much less soybean protein/enzyme-modified phospholipid complex.

These arguments have been extensively addressed before. Applicant argues that Imaizumi, et al. reports on a study carried out to determine if dietary egg yolk phospholipid also exerts a hypocholesterolemic action in rats given a high cholesterol diet and (if) this action is influenced by the constituent fatty acids. The egg yolk phospholipid suppressed the elevation of serum cholesterol irrespective of its fatty acid composition, while purified phosphatidylcholine had no effect, suggesting that the ethanolamine portion is responsible for the hypocholesterolemic effect. These arguments are not found to be persuasive since instant claims recite generic, 'phospholipids' and do not exclude the specific phospholipid, phosphatidylethanolamine taught by Imaizumi and therefore, Imaizumi's teachings that the phospholipids lower the serum cholesterol levels is still applicable. In essence, the references teach that the individual components have an effect on the cholesterol levels and the affidavit filed is not found to be persuasive for the following reasons. Applicant shows in Table 2 the comparisons between soy protein, soy protein hydrolysates, and soy protein hydrolysates/enzyme modified phospholipid complex. First of all, as pointed out before, there are several phospholipases known in Biochemistry (phospholipases, A, C and D for example) and just because phospholipase A2 has some effect, one cannot extrapolate the results to all phospholipases or 'enzymes' in general since they act at different locations in the phospholipid molecule. Secondly, as pointed out above, soy proteins, and phospholipids are known for their effect on cholesterol and the results in Table 2 shows no control values for phospholipids by themselves or phospholipid/soy

protein hydrolysates. Without these controls, one cannot determine the effect observed is the actual effect due to enzyme modified phospholipid complex itself.

3. Claims 18, 35-36, 38, 42-43, 45-46 and 48-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirtori (Ann. Nutr. Metab. 1985) in combination with Sugano (Atherosclerosis, 1988) and Williams (Perspectives in Biology and Medicine, 1984).

Sirtori teaches the effectiveness of lecithinated soy proteins in lowering cholesterol (note the abstract). The amount of lecithin in the complex however, is lower than the amount in instant invention.

Sugano as pointed out before teaches cholesterol lowering activity of the hydrolyzed fractions of soy proteins (abstract).

Williams teaches the effectiveness of phospholipids in cholesterol removal (note the entire article).

It would have been obvious to alter the amounts of the phospholipids in the lecithinated soy proteins in Sirtori with the expectation of obtaining the best possible results since Williams teaches that phospholipids by themselves lower the cholesterol. The use of hydrolyzed fractions of soy protein would have been obvious to one of ordinary skill in the art since even hydrolyzed fractions have the ability to lower the cholesterol as shown by Sugano.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that although Sirtori teaches that low-lipid diet with total

replacement of animal proteins with textured soy proteins containing 6 percent of lecithin reduces serum total cholesterol, Sirtori is silent about the effect of a protein/phospholipid complex and hydrolyzed soy protein. These arguments are not found to be persuasive since Sirtori teaches lecithinated soy protein, which means soy proteins, are in complex form with lecithin (phosphatidylcholine). With regard to the lack of teachings of hydrolyzed proteins, the examiner points out that Sugano's reference teaches the ability of even the hydrolyzed proteins to lower cholesterol. Applicant's arguments that William teaches intravenous administration of lecithin are not found to be persuasive since instant claims do not recite any specific mode of administration. Applicant's arguments that criticality is only necessary where the examiner has established prima facie case of obviousness are not found to be persuasive since the examiner has shown the prior art's teachings of the effectiveness of phospholipids, soy proteins, soy protein hydrolysates and lecithinated soy protein complexes on lowering the serum cholesterol. An enzyme-modified phospholipid is still a phospholipid. Commercially available lecithin contains minor amounts of lysolecithin (formed by the action of phospholipase A) and instant claims do not recite whether the enzyme modification of lecithin is performed on the workbench or the amount and nature of the enzyme modified phospholipid. If applicant is claiming unexpected results, the burden is upon applicant to compare the claimed product with proper controls. The examiner cites US 5,079,028 (col. 1, lines 38-45) and 5,626,873 (col. 1, lines 36-43), which teach that lecithin contains lysophosphatidylcholine.

The rejections are maintained.

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

G S Kishore

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK